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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,333	07/13/2005	John Gary Montana	GJE-7230	7930
23557 7590 06/23/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER SOLOLA, TAOFTQ A				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
06/23/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,333

Applicant(s)

MONTANA ET AL.

Examiner

Taofiq A. Solola

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9, 11-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9, 11-13, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

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Claims 1-9, 11-13, 15 are pending in this application.

Claims 10, 14, 16-21 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The claim is drawn to method of preventing a fertility disorder. The specification fails to provide conclusive evidence that the instant compounds could be used for prevent a fertility disorder. There is no disclosure in the specification on how to identify "normal" people who are predisposed to fertility disorders, and how to treat them so as to prevent the occurrence of the disorders.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for using the instant compounds for the prevention of fertility disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim.

"In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities]

as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965).

"A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973).

Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement." *In re Rasmusson*, 75 USPQ2d 1297 (CAFC 2005). The claimed utility is not enable without undue experimentation for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

"The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims", *In re Rainer*, 146 USPQ 218

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(1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. The specification states:

Compounds of the invention may act as GnRH antagonists. Accordingly, another aspect of the invention is the use of a compound of formula (I) for the manufacture of a medicament for the treatment or prevention of a disease or condition associated with GnRH. The compounds may have utility in the treatment or prevention of a fertility disorder, Alzheimer's disease, HIV infection, AIDS, fibrosis, endometriosis, uterine fibroids, uterine leiomyoma or cancer (e.g. leukemia).

The above statement is speculative at best and therefore, cannot be the basis of support for the instantly claimed utilities.

There is no evidence that the instant compounds would prevent all fertility disorders. No assay is described in the specification.

According to Anderson et al., WO 2000/0202358, antagonist of human GnRH are suitable for treating reproductive disorders and steroid hormone-dependent tumors as well as for regulating fertility where suppression of GnRH is indicated. This statement does not support prevention of all fertility disorders. There is no disclosure in the specification on how to identify "normal" people who are predisposed to fertility disorders, and how to treat them so as to prevent the occurrence of the disorders. There is no disclosure on how to determine the preventive intervention is successful.

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. The purpose of 35 USC 112 is to obviate the need for this type of experimentation. *In re Borkowski*, 164 USPQ

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642 (CCPA, 1970). See also, *Univ. of Rochester v. G.D. Searle & Co*, 68 USPQ2d 1424 (DC WNY, 2003). By deleting "prevention" the rejection would be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., WO 2000/020358, in view of King, Med Chem: Principle and Practice (1994), p. 206-209.

Applicant claims compounds of formula I, their compositions and methods of use.

Determination of the scope and content of the prior art (MPEP 2141.01)

Anderson et al., teach specific species compounds, their compositions and the same methods of use. See compounds in the attached abstract, which are exemplifications of the numerous species by Anderson et al.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Anderson et al., is that in compounds of Anderson et al., applicant replaced >C< with >Si< in the naphthyl ring and -O- with -S- or -N- in the furan ring.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, King teaches that replacement of >C< with >Si< or -O- with -S- or -N- in a ring is expected to produce compounds having similar biological activity (bioisosterism). See page 208, bivalent and tetravalent equivalents. See also, *Ex parte Engelhardt*, 208 USPQ 343

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(Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986). Therefore, the instant invention is prima facie obvious from the teachings of Anderson et al., and King. One of ordinary skill in the art would have known to replace >C< with >Si< or -O- with -S- or -N- in a ring at the time the instant invention was made. The motivation is from knowing that >C< and >Si<; or -O-, -S- and -N- are bioisosteres equivalents.

Response to Argument

Applicant's arguments filed 1/29/08 have been fully considered but they are not persuasive. Applicant contends only through research it can be determined if a modification would results in the same or better activity, and therefore the result is nor predictable. This is not persuasive because the prior art by King provides obvious reason to try the modifications.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,——, 82 USPQ2d 1385, 1397 (2007).

King not only provides limited and finite number of possible modifications, the prior art teaches them as equivalent and are expected to have similar activities. Applicant argues there is no apparent reason to combine elements of the prior arts as claimed, that no suggestion or motivation is in the prior arts to combine the elements, and no expectation of success can be

found in the prior arts. This is not persuasive because King teaches the modifications are expected to yield compounds having similar activities.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

June 19, 2008